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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,536

02/08/2007

Donald Schomer

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07/09/2009

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EXAMINER

DOUGHERTY, SEAN PATRICK

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

07/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,536	Applicant(s) SCHOMER ET AL.	
	Examiner SEAN P. DOUGHERTY	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40,41-43-59,63-67 is/are pending in the application.
- 4a) Of the above claim(s) 44-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40,41,43,50-59 and 63-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/20/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the initial Office action after RCE based on the 10/595536 application filed 02/08/2007. Claims 40, 41, 43-59 and 63-67 are currently pending and have been fully considered below.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/17/2009 has been entered.

Response to Amendment

The amendment(s) filed 03/23/2009 by Applicant have been considered and entered by Examiner.

Examiner acknowledges amended claim(s) 40, 41, 55 and 59, new claim(s) 63-67 and cancelled claim(s) 1-39, 42, 60-62. The previous rejection(s) of claim(s) are maintained. The following reiterated ground(s) of rejection(s) is/are set forth below:

Priority

This application's claim of priority to US Provisional Patent Application Number 60/592,099, filed 07/29/2004, is acknowledged.

Information Disclosure Statement

The information disclosure statement(s) (IDS) submitted on 05/20/2009 is/are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement(s) is/are being considered by Examiner

Election/Restrictions

Claims 44-49 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/07/2008.

The text to the withdrawn claims 44-49 must be included in future presented claims.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

The following claims are objected to because of the following informalities:

Claim 52 recites the limitation(s) "the contrast agent". There is insufficient antecedent basis for this/these limitation(s) in the claim(s) because the limitation(s) has/have not been previously recited in the claim(s).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 64 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Where "the tissue engager does not extend distally beyond the tissue piercing tip" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The specification does not recite where the tissue engager does not extend distally beyond the tissue piercing tip nor do the drawings provide adequate support for where the tissue engager is prevented from extending distally beyond the tissue piercing tip.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 41, 43 and 63-67 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,954,739 to Bonutti.

Regarding claims 40 and 67, Bonutti discloses a kit best seen in Fig. 6 for performing a procedure on a spine, the spine include an epidural space containing a thecal sac, the, kit comprising an insertion member (72) for accessing the epidural space, the insertion member comprising a tissue piercing distal tip (74), and an expandable device (64) sized and shaped to be inserted into the epidural space by an insertion member (col. 8, ll. 18-20) and configured to be expanded (col. 7, ll. 62-64) so as to protect, compress and displace a portion of the thecal sac and provide a safety zone within the epidural space.

Note that the device of Bonutti is capable of performing a procedure on a spine. The expandable device is capable of being expanded into any particular shape as desired for a particular application, therefore, the expandable device of Bonutti is capable of being expanded so as to protect, compress and displace a portion of the thecal sac and provide a safety zone within the epidural space.

Regarding claim 41, note that the insertion member of Bonutti is a cannula as devices are inserted through the insertion member for application in a working space

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Regarding claim 43, Bonutti discloses an injectable medium (col. 2, ll. 33-37).

Regarding claim 63, Bonutti discloses a side aperture located in the distal side of the insertion member (72), defined by the end of the cannula. The expandable device expands on both sides the side aperture on opposite sides of the side aperture, as best seen in Fig. 6.

Regarding claim 64, Bonutti discloses the device best seen in Fig. 6 works as a tool. The tool includes a tissue engager (72) and a tissue cutter (74) which are capable of moving relative to each other. The tissue engager does not extend distally beyond the tissue piercing distal tip when in the position best seen in Fig. 6.

Regarding claim 65, the tissue engager (74) of Bonutti is a needle.

Regarding claim 66, note that the tissue cutter (74) is inserted into the working space by longitudinal movement through the insertion member (col. 15-18). The tissue cutter is part of the tissue piercing distal tip, therefore, they are engaged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 50-52, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,739 to Bonutti, as applied to claim 40 above, in view of US 5,429,136 to Milo et al. (hereinafter "Milo").

Regarding claims 50-52, 57 and 58, Bonutti discloses an injectable medium. Bonutti does not expressly disclose where the injectable medium is an inert base radio-opaque non-ionic myelographic contrast medium.

Milo is a reference in analogous art that discloses a balloon lumen for introducing fluids into the lumen to inflate and deflate the balloon or to introduce other drugs and/or fluids such as radio-opaque fluids (col. 2, ll. 35-40). Bonutti as modified by Milo discloses the claimed invention except for where the radio-opaque fluid is non-ionic and inert. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the radio-opaque fluid both non-ionic and inert, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Such non-ionic and inert fluids would be safe for of imaging within a body in case it accidentally escapes (col. 2, lines 33-37). One having an ordinary skill in the art at the time the invention was made would have found it obvious to modify the injectable fluid of Bonutti to be the an inert base radio-opaque non-ionic myelographic contrast medium of Milo, since the predictable result of

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providing an imaging material within the balloon would ensue. Therefore, a skilled artisan would have found the combination of Bonutti and Milo obvious.

Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,739 to Bonutti, as applied to claim 40 above, in view of US 7,329,402 to Unger et al. (hereinafter "Unger", cited in IDS).

Regarding claims 53-56, Bonutti as modified discloses the claimed invention except for a bio-active agent such as a therapeutic agent such as an anti-inflammatory agent or an anesthetic steroid.

Unger is a reference in analogous art that teaches method of imaging and treating using target compositions (col. 1, ll. 22-26). Unger teaches bioactive agents that refer to a substance which may be used in connection with an application that is therapeutic or diagnostic in nature, including steroids (col. 9, ll. 41-53). Bonutti as modified by Unger discloses the claimed invention except for where the therapeutic agent is an anti-inflammatory agent or an anesthetic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the therapeutic agent an anti-inflammatory agent or an anesthetic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Anti-inflammatory agents and anesthetics are well known therapeutic agents. One having an ordinary skill in the art at the time the invention was made would have found it obvious to include the therapeutic steroids of Unger with the device of

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Bonutti, since the predictable result of targeting tissue for therapeutic applications would ensue. Therefore, a skilled artisan would have found the combination of Bonutti and Unger obvious.

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,739 to Bonutti in view of US 5,985,320 to Edwards et al. (hereinafter "Edwards").

Regarding claim 59, Bonutti discloses a volume of medium in claim 36. Bonutti does not expressly disclose where the volume is injectable at ambient temperatures and more viscous at body temperature.

Edwards is a reference in analogous art that teaches a volume that is injectable at ambient temperatures and more viscous at body temperature. One having ordinary skill in the art at the time the invention was made would have found it obvious to modify the injectable volume of Bonutti to include be viscous at body temperature as taught by Edwards as this modification would provide compositions and methods for enhancing intracellular delivery of bioactive agents (Edwards: col. 2, lines 6-13).

Response to Arguments

Applicant's arguments filed 03/23/2009 have been fully considered but they are not persuasive.

Applicant argues that Bonutti does not disclose an expandable device sized and shaped to be inserted into the epidural space. Applicant also argues that Bonutti does

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not disclose an expandable device configured to protect and displace a portion of the thecal sac.

Examiner disagrees and respectfully notes that structure limitations of the claims are disclosed by Bonutti. It is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Examiner respectfully submits that the reference of Bonutti has not been mischaracterized because the Bonutti is capable of performing such intended functions in the epidural space.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736